DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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DWA

February 7, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 16

John Honkamp
President
Hydrite Chemical Company
300 N. Patrick Boulevard
Brookfield, Wisconsin 53008

Dear Mr. Honkamp:

During our inspection of your Hydrite Chemical Company, an over-the-counter (OTC) drug manufacturing operation located at 7300 W. Bradley Road, Milwaukee, WI, on December 6-7, 1999, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your repacked OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall be followed in the execution of the various production and process control functions [21 CFR 211.100 (a) and (b)] in that (A) process validation has not been conducted on the BZK baby wipe solution manufacturing procedure; and (B) no formal protocol has been prepared for the validation of the D.I. water system which has been initiated.

2. Failure to determine actual yields and percentages of theoretical yield at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall be

performed by one person and independently verified by a second person (21 CFR 211.103). For example, percentages of theoretical yields are not determined at appropriate phases of manufacturing, nor does a second individual verify yields.

3. Failure to assure uniformity from batch to batch by having master production and control records for each drug product prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person [21 CFR 211.186(a)]. For example, all sections of the master formula and production records are not signed by one individual and individually checked, dated, and signed by a second individual for the BZK baby wipe products.

4. Failure of your laboratory records to include complete data derived from all tests necessary to assure compliance with established specifications and standards, including the initials and signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards [21 CFR 211.194(a)(8)]. For example, laboratory records are not reviewed for accuracy, completeness, and compliance with established standards by a second individual for the BZK baby wipe products.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that the Food and Drug administration expects all your locations to be in compliance.

You should notify this office in writing within 15 working days of receipt of this letter of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition, your response to the FDA-483 that was issued to your firm is currently under review.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: Terry Fons
Operations Manager
Hydrite Chemical Company
P.O. Box 23587
Milwaukee, WI 53223-0587